

### **REMARKS**

Reconsideration of this application and entry of this Amendment are requested.

Claims 134-143 will be active in the application subsequent to entry of this Amendment.

Claims 34, 35, 54-57, 59-71, 76-95 and 103-108, all withdrawn from consideration, have been withdrawn without prejudice or disclaimer. The remaining claims have been deleted and a new set inserted.

### **Explanation of the amendments to the claims**

The claims have been amended to more particularly point out and distinctly claim applicants' invention. The wording of new claim 134 is similar to old claim 128, which related to a method of therapeutic or prophylactic treatment comprising the step of implanting tissue compatible resorbable silicon.

There are two main differences between new claim 134 and old claim 128:

(a) new claim 134 now specifies the implantation of a porous silicon implant having a porosity between 4% and 55%; and

(b) new claim 134 also specifies that the implant is allowed to erode for an interval of between one month and one year.

These amendments establish both novelty and inventiveness/nonobviousness based on these two new limitations.

**Basis for the claim amendments**

The basis for the new claims is as follows:

| <i>New claim</i>   | <i>Basis for claim</i>  |
|--------------------|---|
| New claim 134      | PCT claim 1, page 7 (lines 20 to 23), page 25 (lines 13 to 16), and page 3 (lines 15 to 19) |
| New claim 135      | Page 25 (lines 13 to 16)  |
| New claims 136-139 | Page 3 (lines 15 to 19)   |
| New claims 140-143 | PCT claims 19, 20, 13, and 15 respectively  |

**Summary of prior art**

Two items of prior art are cited in the most recent Office Action, namely: WO 97/06101 (Canham et al) and US 3,919,723 (Heinke et al). The "relevant" descriptions of each document is summarized as follows:

WO '101 was discussed in the Amendment of July 17, 2002. The document is again discussed including comments below reflecting the altered wording of claim 134.

WO '101 describes a number of experiments in which samples of porous silicon are immersed in simulated body fluid (SBF). Samples of porous silicon having porosities 18%, 31%, and 48% are described as exhibiting mineral deposition (page 11, lines 1 to 6 and lines 21 to 25 together with page 12, lines 3 to 5). Additionally, this citation reports porous silicon having a porosity of 70% exhibits resorption and no mineralization

(paragraph spanning pages 12 and 13). Also, no resorption was observed for 4% porosity porous silicon (page 13, line 13).

*doesn't really say that, only 4 wks was in SBF*

The possibility of combining porous silicon with calcium in order to promote mineralization is also mentioned (page 14, lines 9 to 10), and an experiment is described in which a sample of 55% porosity porous silicon is combined with calcium (page 14, lines 4 to 9).

US '723 describes prostheses comprising compacted  $\text{Al}_2\text{O}_3$  ceramic for bridging missing parts of a bone or the replacement of joints (column 1, lines 4 to 5). The surface of the prostheses is doped with a substance capable of releasing certain ions. (column 1, lines 4 to 18). A number of ions used to surface dope the  $\text{Al}_2\text{O}_3$  implant are listed, and these include silicon ions (column 2, line 46).

US '723 specifically excludes combining the  $\text{Al}_2\text{O}_3$  implant with the silicon, because this would not provide the silicon in ionic form (column 2, lines 58 to 61).

*No, just not  
merely coating  
see  
Q 48-50*

**Claims 134-143 Are Novel**

**WO '101**

As explained above, the experiments disclosed in WO '101 suggest that certain forms of porous silicon may either corrode or result in mineralization. However, WO '101 does not disclose a method of treatment in which a 4 - 55% porosity porous silicon implant is allowed to corrode over an interval of between one month and one year.

*Agree, w/draw  
102  
103*

It follows that WO '101 does not deprive claims 134-143 of novelty.

**US '723**

Also as explained above, this patent discloses the implantation of  $\text{Al}_2\text{O}_3$  implants that may also include silicon ions. However, US '723 does not disclose a method of treatment in which 4 - 55 % porosity porous silicon implant is allowed to corrode over an

interval of between one month and one year. It follows that US '723 does not deprive claims 134-143 of novelty.

**Claims 134-143 Are Nonobvious**

**WO '101**

The experimental results presented in this published application suggest that porous silicon having porosities between 4% and 55% result in mineralization or no resorption. However, porous silicon having a porosity of 70% shows resorption and no mineralization.

As discussed and explained in the Amendment of July 17, 2002, mineralization can result in the formation a protective barrier (page 17, lines 1 to 2 of WO '101).

The skilled person seeking to deliver a drug for an interval between one month and one year would not select a form of porous silicon that had been shown to promote mineralization or a form of silicon which did not show resorbable properties. This is because the formation of a protective barrier, or lack of corrosion, could prevent delivery of the beneficial substance over the desired time interval.

In other words, it would not be obvious for the skilled person to use porous silicon having porosities between 4 and 55%, since the WO '101 results indicate that these porosities would have relatively undesirable properties in relation to particular problem/objective that the present invention addresses.

WO '101 discloses results showing that high porosities do not result in mineralization, and also showing that erosion increases with increase in porosity. These results would further discourage the use of 4-55% porous silicon.

**US '723 and WO '101**

US '723 describes the treatment of  $\text{Al}_2\text{O}_3$  implants with silicon ions (column 2, line 46). However, the document specifically excludes the combination of  $\text{Al}_2\text{O}_3$  with elemental silicon (column 2, lines 58 to 61). Therefore it would not be obvious to combine these two documents, and it follows that new claim 134 is inventive over a combination of these two documents.

**Response to specific issues raised by the Examiner**

The argument against previous claim 128 appears to be based on the belief that a beneficial substance could, at least to some extent, pass through the protective barrier that results from tissue compatibility.

New claim 134 specifies upper and lower limits to the interval over which the beneficial substance is delivered, and also specifies the use of porous silicon having a specific porosity range. Therefore, were the skilled person to acknowledge the possibility of the beneficial substance passing through the protective barrier, the skilled person would still not use 4-55% porous silicon in the manner defined by claim 1. This is because the beneficial substance has to be delivered over a specific interval, and the presence of the barrier could interfere with this delivery. Further, other WO '101 shows that other forms of silicon are available that do not result in the formation of such a barrier and the skilled person would use these in preference to the 4-55% porous silicon.

*speculative*

For the above reasons it is respectfully submitted claims 134-143 define patentable subject matter. Reconsideration, entry of this Amendment and allowance are solicited.

Respectfully submitted,

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